

FORM PTO-1390
(REV 5-93)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTORNEY DOCKET NO.
026073-00007

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

DATE: July 20, 2007

U.S. APPLN. NO. (IF KNOWN, SEE
37 C.F.R. 1.5) 10/590,479

INTERNATIONAL APPLICATION NO.
PCT/IT05/00088

INTERNATIONAL FILING DATE
February 17, 2005

PRIORITY DATE CLAIMED
February 25, 2004

TITLE OF INVENTION: ANTI-CLUSTERIN OLIGOCLONAL ANTIBODIES FOR DIAGNOSIS AND PREDICTION OF THE AGGRESSIVENESS OF TUMOURS, DIAGNOSTIC METHOD AND RELATED KITS

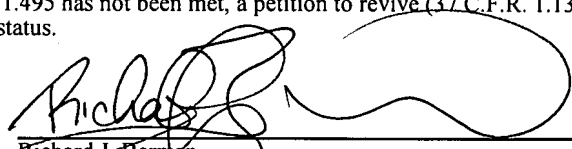
APPLICANT(S) FOR DO/EO/US: Luigi Giusto SPAGNOLI (Nerola, Italy); Sabina PUCCI (Rome, Italy); Elena BONANNO (Rome, Italy); Flavia PICHIORRI (Rome, Italy); and Gennaro CITRO (Rome, Italy)

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The U.S. has been elected (Article 31).
5. ☐ A copy of the International Application as filed [35 U.S.C. 371(c)(2)]
 - a. ☐ is attached hereto (required only if not transmitted by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application into English [35 U.S.C. 371(c)(2)].
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 [35 U.S.C. 371(c)(3)]
 - a. ☐ are attached hereto (required only if not transmitted by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 [35 U.S.C. 371(c)(3)].
9. ☒ An oath or declaration of the inventor(s) [35 U.S.C. 371(c)(4)].
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 [35 U.S.C. 371(c)(5)].

Items 11 to 20 below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98; and Form PTO-SB08.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.
13. ☐ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☒ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Copy of the Notification of Missing Requirements; Statement to Support Filing and Submission in Accordance with 37 C.F.R. 1.821-1.825; Sequence Listing (2 pgs.)

| | | | | | |
|---|--------------|---|--|--|--------------|
| U.S. APPLN. NO. (IF KNOWN, SEE 37 C.F.R. 1.50) 10/590,479 | | INTERNATIONAL APPLICATION NO. PCT/IT05/00088 | | ATTORNEY DOCKET NO. 026073-00007 | |
| The following fees are submitted: | | | | CALCULATIONS | PTO USE ONLY |
| 21. <input checked="" type="checkbox"/> Basic National Fee | | | \$300.00 | \$ 300.00 | |
| 22. <input checked="" type="checkbox"/> Examination Fee If the written opinion prepared by ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) All other situations | | | \$ 0 \$200.00 | \$ | |
| 23. <input checked="" type="checkbox"/> Search Fee If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) Search Fee (37 CFR 1.445(a)(2)) has been paid on the International Application to the USPTO as an International Searching Authority International Search Report prepared and provided to the Office All other situations | | | \$ 0 \$100.00 \$400.00 \$500.00 | \$ | |
| TOTAL OF CALCULATIONS FOR 21, 22 and 23 = | | | | \$ | |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | | Rate | |
| - 100 = | /50 = | | | x \$250.00 | \$ |
| Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date [37 C.F.R. 1.492(e)]. | | | | \$ 130.00 | |
| Claims | Number Filed | Number Extra | Rate | | |
| Total Claims | - 20 = | | x \$ 50.00 | \$ | |
| Independent Claims | - 3 = | | x \$200.00 | \$ | |
| Multiple dependent claim(s) (if applicable) | | | + \$360.00 | \$ | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$ 130.00 | |
| Reduction by one-half for filing by small entity, if applicable. Small entity status under 37 C.F.R. §§1.9 and 1.27 is hereby claimed. | | | | \$ 65.00 | |
| SUBTOTAL = | | | | \$ 65.00 | |
| Processing fee of \$130.00 for furnishing the English translation later the <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date [37 C.F.R. 1.492(f)]. | | | | \$ | |
| TOTAL NATIONAL FEE = | | | | \$ 65.00 | |
| Fee for recording the enclosed assignment [37 C.F.R. 1.21(h)]. The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property | | | | \$ | |
| TOTAL FEES ENCLOSED = | | | | \$ 65.00 | |
| 07/04/2007 GFREY1 00000074 10590479 01 C:2617 65.00 OP | | | | Amount to be refunded | \$ |
| | | | | Charged | \$ |
| a. <input checked="" type="checkbox"/> Check # <u>469862</u> in the amount of \$ 65.00 to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. 01-2300 in the amount of \$ _____ to cover the above fee. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 01-2300. | | | | | |
| NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status. | | | | | |
| SEND ALL CORRESPONDENCE TO: Customer No. 004372 Arent Fox PLLC 1050 Connecticut Avenue, N.W. Suite 400 Washington, D.C. 20036-5339 Tel: (202) 857-6000 Fax: (202) 638-4810 | | | | | |
| | | | |  Richard J. Berman Reg. No. 39,107 | |
| | | | | RJB:mmg | |



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

| U.S. APPLICATION NUMBER NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
|-----------------------------|-----------------------|------------------|
| 10/590,479 | Luigi Giusto Spagnoli | 026073-00007 |

| INTERNATIONAL APPLICATION NO. |
|-------------------------------|
|-------------------------------|

PCT/IT05/00088

| LA. FILING DATE | PRIORITY DATE |
|-----------------|---------------|
|-----------------|---------------|

02/17/2005

02/25/2004

4372
 ARENT FOX PLLC
 1050 CONNECTICUT AVENUE, N.W.
 SUITE 400
 WASHINGTON, DC 20036

CONFIRMATION NO. 9687

371 FORMALITIES LETTER



OC000000024064039

Date Mailed: 05/25/2007

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 08/24/2006
- Copy of the International Search Report filed on 08/24/2006
- Copy of IPE Report filed on 08/24/2006
- Copy of Annexes to the IPER filed on 08/24/2006
- Information Disclosure Statements filed on 08/24/2006
- Biochemical Sequence Listing filed on 08/24/2006
- Request for Immediate Examination filed on 08/24/2006
- U.S. Basic National Fees filed on 08/24/2006
- Priority Documents filed on 08/24/2006
- Specification filed on 08/24/2006
- Claims filed on 08/24/2006
- Abstracts filed on 08/24/2006
- Drawings filed on 08/24/2006
- Paper nucleotide sequence listings filed on 08/24/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath

or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$65 for a Small Entity:

- **\$65 Surcharge.**
- This application does not contain a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). Applicant must provide such statement. If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- **For Rules Interpretation, call (571) 272-0951**
- **For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.**
- **Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov**

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

KAREN R MCLEAN

Telephone: (703) 308-9140 EXT 214

PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/590,479 | PCT/IT05/00088 | 026073-00007 |

FORM PCT/DO/EO/905 (371 Formalities Notice)